510(K) SUMMARY

UC-CARE Warming System

510(k) Number K 090978

Applicant's Name: UC-CARE, Ltd.
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AUG 10 2009

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Trade Name: **UC-CARE Warming System (UCW System)**

Classification:
Name: Unit, Cryosurgical, Accessories
Product Code: GEH
Regulation No: CFR 21 878.4350
Class: II
Panel: General & Plastic Surgery

Device Description:

The UCW System is indicated to transfer heat to the urethral tissue during urological cryosurgical procedures of the prostate. The UCW System includes a **Urethral Catheter & Tubing Set** and a **Warming Kt**

The **Urethral Catheter** is introduced into the bladder to outline the urethral course, and to protect the urethra during therapeutic transperineal, prostatic cryotherapy procedures. The Urethral catheter further transfers heat to the urethral tissue during cryotherapy of the prostate in order to protect the urethra from excessive cold temperatures. The closed loop **Tubing Set** is connected to the catheter's inlet and outlet ports and circulates warm sterile water or saline via the **Warming Kit** that includes a fluid warmer and peristaltic pump.

Intended Use Statement:

The UC-CARE Warming System is indicated to transfer heat to the urethral tissue during urological cryosurgical procedures of the prostate using cryosurgical systems that have been cleared for use on the prostate.

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Date of approval
Endocare Urethral Warming System (Endocare Inc.)	K963970	997125 Feb,
SEEDNET, SEEDNET GOLD, CRYOHIT, CRYO THERA , (PresIce™)	K060390	27 Apr, 2006

Performance Standards:

The UC-Care Warming System has been tested according to various standards and guidance documents, like the ASTM F623-99 (2006) – Standard Performance Specification for Foley Catheter.

Substantial Equivalence:

The UC Care Warming System is as safe and effective as the Endocase Urethral Warming System and the Galil Medical Seednet device. The UC Care Warming System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. Any technological differences between the device and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the UC Care Warming Device is as safe and effective as the predicate devices. Thus, the UC Care Warming Device is substantially equivalent.

Conclusion:

UC-CARE Ltd. believes that, based on the information provided in this submission, the UC-Care Warming System is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

UC CARE, Ltd.
% Mr. Jonathan S. Kahan
Partner
Hogan & Hartson, LLP
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555 Thirteenth Street, N.W.
WASHINGTON DC 20004

AUG 10 2009

Re: K090978
Trade/Device Name: UC CARE Warming System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH and EZL
Dated: August 3, 2009
Received: August 5, 2009

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090978

Device Name: UC CARE Warming System

Indications for Use:

The UC-CARE Warming System is indicated to transfer heat to the urethral tissue during urological cryosurgical procedures of the prostate using cryosurgical systems that have been cleared for use on the prostate.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of General & Plastic Surgery Devices
510(k) Number

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090978